IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., FERRING INTERNATIONAL CENTER S.A., and FERRING B.V., Plaintiffs, v. LUPIN INC., LUPIN ATLANTIS HOLDINGS SA, LUPIN LTD., and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. 1:19-cv-913-RGA

MEMORANDUM OPINION

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/s/ Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Before the Court is Defendants' Motion for Judgment on the Pleadings pursuant to Federal Rule of Civil Procedure 12(c) for failure to state a claim upon which relief may be granted. (D.I. 28). The Court has considered the parties' briefing and letters. (D.I. 29, 37, 43, 48, 50, 62, 65, 67).

I. BACKGROUND

Plaintiffs filed this action on May 16, 2019, alleging infringement of U.S. Patent Nos. 9,827,231 ("the '231 patent") and 9,669,110 ("the '110 patent"). (D.I. 1).[1] The instant action is in response to Defendants filing an ANDA seeking FDA approval for a generic of Plaintiffs' product. (*Id.* at 3). The '231 patent claims a composition of sodium picosulfate, magnesium oxide, citric acid, and malic acid and methods for making and using the composition. ('231 patent, claims 1 and 14). The '110 patent claims a method of timing a colonoscopy procedure. ('110 patent, claim 1). Only the '110 patent is at issue in Defendants' motion for judgment on the pleadings. (D.I. 29 at 1). Claim 1 of the '110 patent recites:

> 1. A method of timing a colonoscopy procedure performed on a patient in need thereof, comprising:
> administering a picosulfate bowel composition to the patient; and
> performing the colonoscopy procedure from about 3 hours to about 1 hour after the administration of the picosulfate bowel composition.

Plaintiff Ferring Pharmaceuticals Inc. holds NDA No. 209589 for sodium picosulfate, magnesium oxide, and anhydrous citric acid for oral solution, marketed as CLENPIQ®. (D.I. 37

[1] Plaintiffs filed an amended complaint on June 17, 2020. (D.I. 89). The parties stipulated that its Count 2, the Count asserting the '110 patent, was unchanged from the original complaint, and that the briefing and arguments made in regard to the original complaint should apply equally to the amended complaint. (D.I. 87).

at 1-2). CLENPIQ® is indicated "for cleansing of the colon as a preparation for colonoscopy in adults." (*Id.* at 2). The CLENPIQ® label describes a "Split-Dose Dosage Regimen," which instructs:[2]

> First dose: administer during evening before the colonoscopy.
> Second dose: administer the next day, during the morning prior to the colonoscopy.

(*Id.*).

Defendants' proposed "ANDA label is substantively identical to the CLENPIQ® label" as required under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(v). (D.I. 29 at 5). The proposed label also instructs that the "highlights do not include all the information needed to use" the picosulfate solution safely and effectively and to "[s]ee full prescribing information." (D.I. 11-2 at 3). The full prescribing information for the Split-Dose method reads:

> **2.2 Split-Dose Dosage Regimen (Preferred Method)**
> The Split-Dose regimen is the preferred dosing method. Instruct patients to take two separate doses in conjunction with fluids, as follows:
>
> <u>Dose 1 – On the day before colonoscopy:</u>
> - Instruct patients to consume only clear liquids (no solid food or dairy) on the day before the colonoscopy up until 2 hours before the time of the colonoscopy.
> - Take the first dose (1 bottle) of Sodium Picosulfate, Magnesium Oxide, and Anhydrous Citric Acid Oral Solution during the evening before the colonoscopy (e.g., 5:00 to 9:00 PM).
> - Follow Sodium Picosulfate, Magnesium Oxide, and Anhydrous Citric Acid Oral Solution by drinking five 8-ounce cups (cup provided) of clear liquids (40 ounces total) within 5 hours and before bed.
> - If severe bloating, distention, or abdominal pain occurs, following the first dose, delay the second dose until the symptoms resolve.

[2] When Defendants' motion was filed, both Ferring's CLENPIQ® label and Defendants' proposed label included an alternative "Day-Before Dosage Regimen." (*See* D.I. 29 at 5). In October 2019, the CLENPIQ® label was revised to remove this alternative dosing method. (D.I. 62). Defendants will have to amend their proposed ANDA product label to conform with this change. (*Id.*). I will thus only consider the "Split-Dose" method, which, as Plaintiffs pointed out, is the basis for Plaintiffs' induced infringement claim. (D.I. 37 at 2).

Dose 2 – Next morning on the day of colonoscopy (start approximately 5 hours prior to colonoscopy):

- Continue to consume only clear liquids (no solid food or dairy).
- Take the second dose (the second bottle) of Sodium Picosulfate, Magnesium Oxide, and Anhydrous Citric Acid Oral Solution.
- Following the Sodium Picosulfate, Magnesium Oxide, and Anhydrous Citric Acid Oral Solution dose, drink at least three 8-ounce cups (cup provided) of clear liquids (24 ounces) at least 2 hours before the colonoscopy.

(D.I. 11-2 at 6-7).

Plaintiffs allege that physicians and patients who use Defendants' ANDA product in accordance with its label will directly infringe the claims of the '110 patent by "performing the colonoscopy from about 3 hours to about 1 hour after administration of the picosulfate bowel composition." (D.I. 37 at 9). Thus, Plaintiffs claim that Defendants will indirectly infringe the '110 patent under 35 U.S.C. § 271(b) by inducing physicians who prescribe picosulfate solution, or patients who take it, to directly infringe. (*Id.* at 8).

II. LEGAL STANDARD

A motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is reviewed under the same standard as a Rule 12(b)(6) motion to dismiss when the Rule 12(c) motion alleges that the plaintiff failed to state a claim upon which relief can be granted. *See Turbe v. Gov't of the Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991); *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010). The court must accept the factual allegations in the complaint and take them in the light most favorable to the non-moving party. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). "When there are well-ple[d] factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). The court must "draw on its judicial experience and common sense" to make the determination. *See id.* In ruling on a

motion for judgment on the pleadings, the court is generally limited to the pleadings. *Mele v. Fed. Reserve Bank of N.Y.*, 359 F.3d 251, 257 (3d Cir. 2004). The court may, however, consider documents incorporated into the pleadings and those that are in the public record. *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

III. DISCUSSION

Defendants seek judgment on the pleadings regarding Plaintiffs' induced infringement claims for the '110 patent.[3] (D.I. 29 at 1). Defendants argue that Plaintiffs' "complaint fails to state a claim [for induced infringement] because [Defendants'] ANDA label does not encourage, recommend, or promote anyone to perform the claimed use" of the '110 patent. (*Id.* at 8).

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. 271(b). "To prove inducement, a plaintiff must present evidence of active steps taken to encourage direct infringement; mere knowledge about a product's characteristics or that it may be put to infringing uses is not enough." *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, 940 F.3d 680, 701 (Fed. Cir. 2019). Inducement liability can be found when "instructions teach an infringing use . . . such that we are willing to infer from those instructions an affirmative intent to infringe the patent." *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (emphasis omitted). In ANDA cases, to determine whether affirmative intent can be inferred from the label, courts assess whether the proposed label "encourage[s], recommend[s], or promote[s] infringement." *Id.* "Merely describing the infringing use, or

[3] Defendants' motion also seeks judgment on the pleadings for Plaintiffs' supposed claim of contributory infringement of the '110 patent, but Plaintiffs have stated that they do not seek declaratory judgment for such a claim. (D.I. 29 at 1; D.I. 37 at 8 n.1). Thus, I need not and do not consider Defendants' contributory infringement arguments.

knowing of the possibility of infringement, will not suffice; specific intent and action to induce infringement must be shown." *HZNP Medicines*, 940 F.3d at 702.

Defendants argue that nothing in their proposed "ANDA label 'encourages, recommends, or promotes' administration of the picosulfate solution about 1 to 3 hours before the colonoscopy begins, as required by every claim of the '110 patent." (D.I. 29 at 10). It is undisputed that Dose 1 of the Split-Dose Regimen, which is to be taken the day before the colonoscopy, does not infringe the '110 patent. (*Id.*; *see* D.I. 37 at 8-9). Thus, that portion of Defendants' label does not induce infringement. Regarding Dose 2, Defendants argue that because the label instructs physicians and patients to see the full prescribing instructions, and the full prescribing instructions direct that the 5.41-fluid ounce dose should be started "approximately 5 hours prior to colonoscopy," the label therefore does not "encourage, recommend, or promote" that Dose 2 be taken less than 3 hours before the colonoscopy. (D.I. 29 at 11). Defendants continue that, even if "a patient could still be drinking the 5.41-fluid ounce dose within three hours of the colonoscopy" because the label is interpreted to "describe" or "permit" this use, the label does still not rise to the level of inducement because it is not encouraging, recommending, or promoting such use. (*Id.*). Defendants claim that Plaintiffs cannot "create a material issue of fact" by asserting that it is possible for doctors and patients to infringe without showing that the label promotes or encourages that possible infringement. (*Id.* at 12).

Plaintiffs counter that they allege "facts in the Complaint that, when accepted as true and viewed in a light most favorable to [Plaintiffs], plausibly demonstrate that [Defendants] will induce infringement of the '110 patent." (D.I. 37 at 8). Plaintiffs argue that, as a result of following Defendants' label, which instructs to take Dose 2 the "next day, during the morning prior to the colonoscopy," some doctors and patients will directly infringe the '110 patent claims.

(*Id.* at 8-9). Plaintiffs state that "there is no absence of evidence" that Defendants' label will "promote and encourage physicians and patients to infringe through these instructions." (*Id.* at 9). Because Plaintiffs and Defendants have different interpretations of the label's instructions, Plaintiffs contend that there are disputed issues of material fact which require discovery to discern how physicians and patients will interpret and follow Defendants' label's instructions. (*Id.* at 10-11).[4]

I do not see why discovery is necessary to determine whether Defendants' proposed ANDA label encourages, recommends, or promotes an infringing use. The label does not do so. On its face, the label does not instruct that the Dose 2 picosulfate solution be administered less than 3 hours and more than 1 hour before the colonoscopy procedure. The label states that Dose 2 should be taken the "next day, during the morning of the colonoscopy." This instruction does not encourage, recommend, or promote that the solution should be administered during the infringing timeframe, nor does it even require or contemplate the infringing timeframe. Instead, it is a broad guideline for safe and effective timing of the second dose. The full prescribing

[4] Plaintiffs also argue that because the Court previously decided that a dispute of material fact existed in a related and factually similar case, I should do so again here. (D.I. 37 at 11). In that case (17-cv-894), the same Plaintiffs alleged in Count III that Defendants Novel Laboratories and Gavis Pharmaceuticals would induce infringement of the '110 patent by the proposed label on their ANDA product. Defendants filed a motion for judgment on the pleadings, which, in relevant part, argued that the Court lacked subject matter jurisdiction over the Count III claims. (17-cv-894, D.I. 16; D.I. 17). The relevant inquiry in resolving the motion was not whether the proposed ANDA label encouraged, recommended, or promoted infringement, but rather whether there was an actual controversy between the parties or if any infringement was merely speculative. (17-cv-894, D.I. 59 at 10-11; *see also id*., D.I. 17 at 2-3 (summarizing Defendants' argument)). The Magistrate Judge determined, and I adopted without objection, that there was an actual controversy because material facts were disputed between the parties as to whether the label could result in some physicians or patients infringing the '110 patent. (*Id.* at 12). Plaintiffs now argue that this holding should apply in the instant case. I do not think it should. That determination did not consider the same inquiries that are central to the matter here, namely whether the proposed label encourages, recommends, or promotes infringement of the '110 patent.

instructions further indicate that the second dose should be taken starting approximately five hours before the colonoscopy. The final step of the Split-Dose Regimen instructs that the patient should drink at least 24 ounces of clear liquid following the picosulfate solution but "at least 2 hours before the colonoscopy." Logically, the instruction for the final step would require consumption of the picosulfate solution more than 2 hours before the colonoscopy. That instruction therefore cannot be interpreted as encouraging, recommending, or promoting consumption of the picosulfate solution less than 3 hours before the colonoscopy. The mere fact that the label may permit an infringing use is insufficient to show inducement, regardless of whether that fact is alleged in the complaint or stated later by an expert. *See HZNP Medicines*, 940 F.3d at 702. The only reasonable reading of the full prescribing instructions is that they say to take the picosulfate solution no more than 5 hours before the colonoscopy and to finish it no later than 2 hours before the colonoscopy. The label, with or without the full prescribing instructions, therefore provides no basis for the inference that it is telling physicians and patients to start about 3 hours before and to end no later than 1 hour before the colonoscopy. Thus, Defendants' label cannot be the basis for a finding of any affirmative action or intent to induce infringement.

Furthermore, Plaintiffs do not allege any facts to support the conclusion that the label encourages, recommends, or promotes the infringement of the '110 patent. (*See* D.I. 37 at 8-11). Thus, Plaintiffs have failed to meet their burden of establishing a plausible claim of Defendants' inducement. Plaintiffs' allegations assert only that some physicians or patients will infringe the patent as a result of following the label's instructions (*id.* at 9), but whether some direct infringement will occur is not the standard for determining inducement in the instant case. *See Takeda*, 785 F.3d at 630-31. Plaintiffs contend that because the label's instruction to "continue

to consume only clear liquids" comes before the instruction to "take the second dose," the second dose is not necessarily started "approximately 5 hours prior to colonoscopy."[5] (D.I. 37 at 10). Taking this contention as true and assuming that Dose 2 is administered less than 5 hours before the colonoscopy, this instruction does not rise to the level of encouraging, recommending, or promoting taking the second dose less than 3 hours, and more than 1 hour, before the colonoscopy. Plaintiffs do not argue that it does, nor do they argue that any other portion of the label encourages, recommends, or promotes an infringing use. (*See id.* at 9-10).

Plaintiffs claim that "there is no 'absence of evidence' that [Defendants] will 'promote and encourage physicians and patients to infringe though [the label's] instructions.'" (D.I. 37 at 9). Plaintiffs, however, do not suggest what this evidence might be. (*See id.*). Plaintiffs also contend that discovery is needed to understand "how physicians and patients will interpret and follow the instructions," suggesting that "at least some physicians . . . will instruct their patients to administer, and at least some patients . . . will administer [Defendants' product] in an infringing manner." (*Id.* at 11, 17). But Plaintiffs do not claim that discovery will produce evidence that the label encourages, recommends, or promotes an infringing use. (*See id.* at 9-11, 17). There is no genuine dispute of material fact as to whether Defendants' proposed ANDA product label recommends, encourages, or promotes an infringing use. It does not, and therefore Defendants' label does not induce infringement of the '110 patent.[6]

[5] The Complaint alleges infringement under the doctrine of equivalents (D.I. 1, ¶¶ 53, 55-56) and Plaintiffs' brief quotes one of those allegations (D.I. 37 at 4). Plaintiffs do not make any argument that the boilerplate DOE allegations have any impact on the arguments relating to the motion at issue.

[6] I note that Defendants offered two other reasons why Plaintiffs did not state a claim for induced infringement: (1) the method claimed in the '110 patent is not FDA-approved, and (2) Defendants' proposed label provides for substantial noninfringing uses. Because I determine as a matter of law that Defendants' label does not induce infringement under the standard set out by the Federal Circuit, I will not address Defendants' remaining two arguments.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' Motion for Judgment on the Pleadings. (D.I. 28). An accompanying order will issue.